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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,308	01/10/2001	Howard A. Fields	14114.0349U2	9952

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EXAMINER	
LI, BAO Q	
ART UNIT	PAPER NUMBER
1648	7

DATE MAILED: 12/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,308	FIELDS ET AL.	
	Examin r	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Preliminary amendment is acknowledged. Claims 7 and 9-13 are amended and entered. Claims 1-25 are pending.

Election/Restrictions

Applicant's election with traverse of Group II, claims 7-10 within the scope of the amino acids 1-91 of the hepatitis C virus (HCV) core protein Paper No. 7 is acknowledged. The traversal is on the ground(s) that the examiner has not shown a serious burden for examining all claims together. Applicants also asserted that claims 11-13 are dependent claims of the claim 7; therefore they should be examined with group II, claims 7-12.

Upon reviewing the retracted groups, examiner agrees to rejoin the claims 11-13 to the elected group II, claims 7-10.

However, it constitutes a serious burden for examining all groups of the inventions for the reason as described in the previous office action.

Therefore, claims 7-13 are considered.

Applicants are required to cancel the claims 1-6 and 14-25 to the non-elected groups.

Claim Objections

Claim 13 is objected to because of the following informalities: the phrase of " comprise amino acid residues 1471-1573 of the HCV polypeptide" is a typo because it is not associated with any claimed language. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is unclear for recitation of HCV and NS. Please spell the full names of HCV and NS followed by the short abbreviation in the parenthesis.

Claim 7 is vague and indefinite in that the metes and bonds of " one or more antigen epitopes" are not defined. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, because there are many antigen epitopes in the regions of HCV core, NS3 and NS4 proteins, the claims should point out which epitope is intended in the said claim.

In addition, claims 7-13 render in definite for reciting, " comprising" to define the mosaic peptide structure and antigen epitope structure. However, the word "comprising" use here is an open language, which fails to define any precise amino acid sequence structure. The claims should use more defined language to describe the novelty of the intended amino acid sequence structure of the peptide or epitope in the said claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7 is rejected under 35 U.S.C. 102(b) as anticipated by Chien et al. (a) (P.N.A.S. USA. 1992, Vol. 89, pp. 10011-10015).

Chien et al. teach a fusion protein comprising a sequence structures of NS3, NS4 and nucleocapside protein C (core protein) fragments. Therefore, the claimed invention is anticipated by the cited reference (see entire document). Therefore, the claimed invention is anticipated by the cited reference.

Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by Chien et al. (b) (J. Gastro. Hepto. 1993, Vol. 8, pp. S33-39).

Chien et al. teach a general method for using recombinant antigen polypeptide antigen (C25) comprising six proteins representing the structural regions of core, the envelope and non-structural regions (C33C) and NS3-NS4 (C11-3) and NS5 to detect the anti-HCV antibody by using immunoassay techniques. Chien et al demonstrate that the C25 enzyme-linked immunosorbent assay (ELISA) has improved the assay sensitivity, which is able to identify additional HCV antibody reactivity in both hepatocellular carcinoma and cryptogenic cirrhosis patients. They concluded that the assay of using the combined antigens is superior to the single peptide assay that is performed poorly in the detection of the single peptide C33C only reactive sample (see entire document). Therefore, the claimed invention is anticipated by cited reference.

Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by Valenzuela et al. (WO 97/44469 A2).

Valenzuela et al. teach a multiple copy epitope sequence having the general structural formular (I): (A)x-(B)y-(C)z, wherein the (I) is a linear amino acid sequence and the A. B. and C, are epitopes from the regions of the HCV polyprotein. The said regions are selected fro the group consisting of NS3, NS4, NS5, c100, C25, core, E1, E2, c33c, c100-3 and c22. Velenzuela et al. also disclose that the multiple epitope polypeptide are used as a composition for detecting the HCV infection (see claims 1, 5 and 12) Therefore, the claimed invention is anticipated by the cited reference

(For the above rejection, the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (P.N.A.S. USA. 1992, Vol. 89, pp. 10011-10015) and Kato et al. (P.N.A.S. USA. 1990, Vol. 87, 9524-9528).

Claimed invention is drawn to a mosaic polypeptide comprising one or more epitopes from each of the hepatitis virus (HCV) core protein, non-structural protein 3 (NS3) and NS4, wherein the core is amino acids sequence 1-91, NS3 are 1471-1573 and 1789-1867, NS4 are1789-1867 and 1916-1948.

Chien et al. (a) teach a fusion protein comprising the sequence structures of NS3 fragment, NS4 fragment and nucleocapside protein C (core protein) fragments. Chien et al. differ in that they do not disclose the precise amino acid sequences in the construct.

However, the amino acid sequences corresponding to each of the claimed structures of the HCV are not only known in the art as evidenced by Kato et al. who disclose all the claimed sequences from claims 7, 9-12 with 100% homology (See entire document) but also are well characterized as evidenced by Chien et al. supra (a).

Therefore, in order to get better sensitivity for detecting the HCV infection or get better immunogenicity for inducing an immune response, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited reference of Chien et al (a). and in further view of sequences the disclosed by Kato et al to make a mosaic polypeptide comprising HCV core, NS3 and NS4 for detecting the anti-HCV antibodies with an improved higher sensitivity without unexpected results. Hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Claims 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (b) (J. Gastro. Hepto. 1993, Vol. 8, pp. S33-39) and Kato et al. (P.N.A.S. USA. 1990, Vol. 87, 9524-9528).

Claimed invention is drawn to a mosaic polypeptide comprising one or more epitopes from each of the hepatitis virus (HCV) core protein, non-structural protein 3 (NS3), NS4 and NS5), wherein the core is amino acids sequence 1-91, NS3 are 1471-1573 and 1789-1867, NS4 is 1789-1867 and 1916-1948 and NS5 is 2322-2423.

Chien et al. teach a general method for using recombinant antigen polypeptide antigen (C25) comprising six proteins representing the structural regions of core, the envelope and non-structural regions (C33C) and NS3-NS4 (C11-3) and NS5 to detect the anti-HCV antibody by using immunoassay techniques. Chien et al demonstrate that the C25 enzyme-linked immunosorbent assay (ELISA) has an improved assay sensitivity and is able to identify additional HCV antibody reactivity in both hepatocellular carcinoma and cryptogenic cirrhosis patients. They concluded that the C25 assay is superior to the single peptide assay that is performed poorly in the detection of the single peptide C33C only reactive sample (see entire document). Chien et al. differ in that they do not disclose the precise amino acid sequences in the construct.

However, the amino acid sequences corresponding to each of the claimed structures of the HCV are not only known in the art as evidenced by Kato et al. who disclose all the claimed sequences from claims 7, 9-12 with 100% homology (See entire document) but also are well characterized as evidenced by Chien et al. supra (b).

Therefore, in order to get better sensitivity for detecting the HCV infection or get better immunogenicity for inducing an immune response, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited reference of Chien et al (b). and in further view of sequences the disclosed by Kato et al to make a mosaic polypeptide comprising HCV core, NS3, NS4 and NS5 for detecting the anti-HCV antibodies with an improved higher sensitivity without unexpected results. Hence, the claimed invention as a whole is prima facie obvious absence unexpected results.

Claims 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valenzuela et al. (WO 97/44469 A2) and in further view of Chien et al. (b) (J. Gastro. Hepto. 1993, Vol. 8, pp. S33-39) and Kato et al. (P.N.A.S. USA. 1990, Vol. 87, 9524-9528).

Claimed invention is drawn to a mosaic polypeptide comprising one or more epitopes from each of the hepatitis virus (HCV) core protein, non-structural protein 3 (NS3), NS4 and NS5), wherein the core is amino acids sequence 1-91, NS3 are 1471-1573 and 1789-1867, NS4 is 1789-1867 and 1916-1948 and NS5 is 2322-2423.

Valenzuela et al. teach a multiple copy epitope sequence having the general structureal formular (I): (A)x-(B)y-(C)z, wherein the (I) is a linear amino acid sequence and the A. B. and C, are epitopes from the regions of the HCV polyprotein. The said regions are selected fro the group consisting of NS3, NS4, NS5, c100, C25, core, E1, E2, c33c, c100-3 and c22. Velenzuela et al. also disclose that the multiple epitope polypeptide are used as a composition for detecting the HCV infection (see claims 1, 5 and 12). Valenzuela et al. differ in that they do not disclose the precise amino acid sequences in the construct.

However, the amino acids sequences encoding each of the polyproteins are not only fully disclosed as evidenced by Kato et al. who disclose all the claimed sequences from claims 7-13 with 100% homology, but are also well studied for their immunogenicity, especially with combinated antigen epitopes as evidenced by Chien et al. (b), who teach a general method for using a recombinant antigen polypeptide (C25) comprising six proteins representing the structural regions of core, the envelope and non-structural regions (C33C) and NS3-NS4 (C11-3) and NS5 to detect the anti-HCV antibody .Chien et al (b) demonstrate that the C25 enzyme-linked immunosorbent assay (ELISA) has improved the assay sensitivity and is able to identify additional HCV antibody reactivity in both hepatocellular carcinoma and cryptogenic cirrhosis patients. They concluded that the C25 assay is superior to the peptide assay that performed poorly in the detection of the single peptide C33C only reactive sample.

Therefore, in order to get better sensitivity for detecting the HCV infection or get better immunogenicity for inducing an immune response, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited reference of Valezuela et al. and in further view of the teaching of Chien et al. (b) and the sequences disclosure by Kato et al to make a mosaic polypeptide comprising HCV core, NS3, NS4 and NS5 for detecting the anti-HCV antibodies with an improved higher sensitivity without unexpected results. Hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
December 21, 2001

ALI R. SALIMI
PRIMARY EXAMINER